GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

May 14, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002; Interim Final Rule; Reopening of Comment Period; Docket No. 02N-0276.

Comments of the Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to provide further comments on implementation of the food facility registration under section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act").

Grocery Manufacturers of America is the world's largest association of food, beverage and consumer product companies. Led by a board of 46 Chief Executive Officers, GMA applies legal, scientific and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states.

Overall, GMA members have had a positive experience with the food facility registration system. In general, members have found the process to register to be straightforward and efficient. There are a few aspects of the registration process that warrant comment, however.

2002N-0276 C234

First, some companies have encountered situations in which persons who are not authorized to register a facility have nevertheless done so. In some instances, the problem was discovered by the facility when FDA sent a confirmation of registration to the facility. It does not appear, however, that facilities are routinely informed when a registration is first made or later updated. We suggest that FDA adopt the practice of routine notification to facilities (or to the designated communication person) when a registration is made or modified.

A similar problem involves the designation of U.S. agent by foreign facilities. We understand that FDA has sent emails to U.S. agents when they are designated by a facility to confirm that the agent has accepted the designation. It is not clear that FDA is doing this routinely and reports of agents who have been designated without their knowledge or consent continue to circulate. FDA should provide a mechanism to ensure that all agents who have been designated by a foreign facility accept the designation.

There have been some instances in which FDA communications concerning facility registration have not been directed to the contact person designated on the registration. GMA requests that FDA makes certain that its registration computer system is designed to ensure that communications are directed to the person that the registrant has identified as the contact person.

It appears from FDA's published data on facility registration that far fewer facilities have registered than FDA expected. There may be several reasons why this is true, including the possibility that the initial estimates of the number of facilities subject to the registration requirement were high. Nevertheless, we suggest that FDA undertake additional education and outreach programs to ensure that all persons who operate facilities that need to be registered are, in fact, aware of the requirement.

In conclusion, GMA commends FDA for creating a workable registration system.

Sincerely,

Susan M. Stout

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